

TRANSLATION

PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter II of the Patent Cooperation Treaty)

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 12726801001	FOR FURTHER ACTION	See Form PCT/IPEA/416
International application No. PCT/IB2004/004224	International filing date (<i>day/month/year</i>) 21.12.2004	Priority date (<i>day/month/year</i>) 23.12.2003
International Patent Classification (IPC) or national classification and IPC C12P19/04, C12P19/98, C08B37/00, C12N1/20, C12N 9/10, A23L1/054		
Applicant UNIVERSIDAD NACIONAL DE COLOMBIA		

1. This report is the international preliminary examination report, established by this International Preliminary Examining Authority under Article 35 and transmitted to the applicant according to Article 36.
2. This REPORT consists of _____ sheets, including this cover sheet.
3. This report is also accompanied by ANNEXES, comprising: a. <input checked="" type="checkbox"/> (sent to the applicant and to the International Bureau) a total of 15 sheets, as follows: <input checked="" type="checkbox"/> sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications authorized by this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions). <input type="checkbox"/> sheets which supersede earlier sheets, but which this Authority considers contain an amendment that goes beyond the disclosure in the international application as filed, as indicated in item 4 of Box No. I and the Supplemental Box. b. <input type="checkbox"/> (sent to the International Bureau only) a total of _____, containing a sequence listing and/or tables related thereto, in computer readable form only, as indicated in the Supplemental Box Relating to Sequence Listing (see Section 802 of the Administrative Instructions).
4. This report contains indications relating to the following items: <input checked="" type="checkbox"/> Box No. I Basis of the report <input type="checkbox"/> Box No. II Priority <input type="checkbox"/> Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability <input type="checkbox"/> Box No. IV Lack of unity of invention <input checked="" type="checkbox"/> Box No. V Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement <input type="checkbox"/> Box No. VI Certain documents cited <input type="checkbox"/> Box No. VII Certain defects in the international application <input checked="" type="checkbox"/> Box No. VIII Certain observations on the international application

Date of submission of the demand	Date of completion of this report
Name and mailing address of the IPEA/ES	Authorized officer
Facsimile No.	Telephone No.

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Box No. I

Basis of the report

1. With regard to the **language**, this report is based on the international application in the language in which it was filed, unless otherwise indicated under this item.
- ☐ This report is based on translations from the original language into the following language _____, which is the language of a translation furnished for the purposes of:
- ☐ international search (Rule 12.3 and 23.1(b))
- ☐ publication of the international application (Rule 12.4)
- ☐ international preliminary examination (Rule 55.2 and/or 55.3)
2. With regard to the **elements** of the international application, this report is based on *(replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report)*:
- ☐ the international application as originally filed/furnished
- ☒ the description:
- pages 1, 2, 4 8-10, 12, 15, 19, 2 as originally filed/furnished
- pages* 3, 5, 6, 7, 11, 13, 14, 16, 17, 18 received by this Authority on _____
- pages* _____ received by this Authority on _____
- ☒ the claims:
- nos. _____ as originally filed/furnished
- nos.* _____ as amended (together with any statement) under Article 19
- nos.* 20-24 received by this Authority on 04.10.2005
- nos.* _____ received by this Authority on _____
- ☐ the drawings:
- sheets _____ as originally filed/furnished
- sheets* _____ received by this Authority on _____
- sheets* _____ received by this Authority on _____
- ☐ a sequence listing and/or any related table(s) – see Supplemental Box Relating to Sequence Listing.
3. ☐ The amendments have resulted in the cancellation of:
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____
4. ☐ This report has been established as if (some of) the amendments annexed to this report and listed below had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).
- ☐ the description, pages _____
- ☐ the claims, nos. _____
- ☐ the drawings, sheets/figs _____
- ☐ the sequence listing (*specify*): _____
- ☐ any table(s) related to sequence listing (*specify*): _____

* If item 4 applies, some or all of those sheets may be marked "superseded."

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Box No. V	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
1.	Statement		
	Novelty (N)	Claims <u>1-18</u>	YES
		Claims _____	NO
	Inventive step (IS)	Claims <u>1-18</u>	YES
		Claims _____	NO
	Industrial applicability (IA)	Claims <u>1-18</u>	YES
		Claims _____	NO
2.	Citations and explanations (Rule 70.7)		
	Documents taken into consideration:		
	D1: Manca; M. C. et al. Milchwissenschaft, 1985, vol. 40 (7) 1985		
	D2: WO 0157234 A2 2001		
	D3: De Vuyst, L. D. et al. International Dairy Journal, vol. 11 (9) 2001		
1.	Novelty and inventive step		
	<p>Independent claim 1 of the present patent application relates to a glucose and fructose biopolymer (prepared using an enzymatic preparation that produces <i>Lactococcus lactis</i> strain NRLL B-300656). The claim includes a series of physical and chemical properties of the biopolymer, including the relative proportions of the glucose and fructose monosaccharides, namely 0.2 to 0.7, and the molecular weight of the biopolymer, namely 900 to 1100 Kd.</p> <p>Claim 2 relates to the method for making the enzymatic preparation from microorganism</p>		

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	<p><i>Lactococcus lactis</i> NRLL B-300656. Claims 3 to 7 are dependent claims in which details of the production method are specified. The enzymatic preparation, which has glucosyl transferase and fructosyl transferase activity, is used to achieve the previously claimed biopolymer.</p> <p>Claim 8 relates to the method for making the biopolymer of claim 1 by incubating the enzymatic preparation obtained in claims 2 to 7. The method comprises incubating the enzymatic extract under suitable conditions then recovering and purifying the biopolymer. Claim 9 specifies the conditions under which the enzymatic preparation is incubated, and claims 10 and 11 relate to two methods for recovering and purifying the biopolymer.</p> <p>Claims 12 to 15 relate to <i>Lactococcus lactis</i> bacterial strain NRLL B-300656. Claim 15 relates to the same microorganism but in preserved form.</p> <p>Finally, claims 16 to 18 mention the possible uses of the biopolymer in industry.</p> <p>Document D1 describes an extracellular polysaccharide with around 1000 hexoses, consisting of glucose and fructose, with a ratio of glucose to fructose of 0.5, a value that falls within the same range as that of the biopolymer of the present application. However, the molecular weight of said heteropolysaccharide is 197</p>

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	<p>kilodaltons, i.e. lower than that of the invention. The microorganism that produces the biopolymer is a lactic acid bacterium but of a different species, specifically <i>Lactococcus bulgaricus</i>.</p> <p>A <i>Lactococcus lactis</i> strain that produces a heteropolysaccharide but consists of glucose and galactose is described in document D2. In addition to other genes that code for enzymes involved in the biosynthesis of the heteropolysaccharide, the microorganism has genes that code for enzymes galactosyl transferase and glucosyl transferase.</p> <p>Document D3 is a review of heteropolysaccharides produced by lactic acid bacteria. Most of the biopolymers consist of glucose, galactose and ramnose, and fructose was found to be present in only one instance. The methods for biosynthesising said compounds require, in addition to the transferases for the component monosaccharides of the heteropolysaccharide, a set of enzymes having other functions such as carrier enzymes, polymerising enzymes, etc.</p> <p>No prior art document describes a biopolymer such as that of claim 1, or a microorganism from species <i>Lactococcus lactis</i> capable of producing an enzymatic preparation having glucosyl transferase and fructosyl transferase activity.</p> <p>Furthermore, the prior art does not contain indications that suggest that a microorganism from</p>

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	<p>species <i>Lactococcus lactis</i> might produce said biopolymer or said enzymatic preparation.</p> <p>As a result, independent claims 1, 2 and 12 are considered to comply with the requirements of novelty and inventive step. It follows that dependent claims 3 to 7 and 13 to 15 are also novel and involve an inventive step.</p> <p>Both the method for preparing a novel biopolymer (claim 8 and dependent claims 9 to 11) and the uses thereof (claims 16 to 18) can also be considered to be novel and inventive.</p> <p>2. Industrial applicability</p> <p>All of the claims (1 to 18) are industrially applicable.</p>

Box No. VIII Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:

1. Some of the claims are not supported by the description, or there is an inconsistency between the content of the description and that of the claims.

For example:

- Claim 3: It is indicated on page 5 of the description that the activation of the microorganism is carried out at 20 to 40 °C. A temperature of 30 °C is mentioned on page 11. No further information is provided in the description in support of a claim in which the temperature is 25 °C.
- Claim 4: the fermentation step is mentioned on page 5 and the aeration rate (0.1 to 1 vvm) and pH (5-9) are specified. The fermentation conditions are repeated in the table on page 13. The aeration rate given in the table falls outside the previously indicated range. The time given in the table is 6 to 12 hours, whereas the interval claimed is 12 to 36 hours, which thus falls outside said range.
- Claim 5: Centrifuging to recover the enzyme is carried out at 3000 to 10000 rpm on page 6 but at 3000 to 7000 rpm in claim 5.
- Claim 6: On page 11, the preinoculum preparation time is 12 to 24 hours on page 11, and not 12 to 36 hours as in claim 6.
- Claim 7: The concentrations of the components of

Box No. VIII

Certain observations on the international application

the medium are specified, but in the final part it is indicated that they are incubated for 10 to 36 hours and the pH conditions, etc., are repeated. To which step does this time interval refer and where is it found in the description?

- Claim 10: The air temperature in the biopolymer drying step is 50 to 80 °C in the claim, but in the only indication provided on this matter in the description is that the temperature is 60 °C on page 7 and 60 to 80 °C on page 14.

2. Lack of clarity of some of the claims.

- Claim 1: The preamble of the claim is unclear. The claim is a product claim relating to a material (a biopolymer) characterised in terms of its physical and chemical properties. The method for preparing said material does not define features of the material and is thus irrelevant to this claim. If a reference to the origin of the biopolymer is to be retained, it should be clarified, e.g. in accordance with the wording on page 3, lines 1-3: "A biopolymer produced by an enzymatic extract having glucosyl transferase and fructosyl transferase activity prepared from *Lactococcus lactis* strain NRLL B-300656", characterised in that the biopolymer..

- Claims 16 to 18 relate to uses of the biopolymer and should be worded accordingly.